



## General

#### **Guideline Title**

ACR Appropriateness Criteria® imaging for transcatheter aortic valve replacement.

## Bibliographic Source(s)

Leipsic JA, Blanke P, Hanley M, Batlle JC, Bolen MA, Brown RKJ, Desjardins B, Eberhardt RT, Gornik HL, Hurwitz LM, Maniar H, Patel HJ, Sheybani EF, Steigner ML, Verma N, Abbara S, Rybicki FJ, Kirsch J, Dill KE, Expert Panel on Cardiac Imaging and Vascular Imaging. ACR Appropriateness Criteria® imaging for transcatheter aortic valve replacement. Reston (VA): American College of Radiology (ACR); 2017. 8 p. [48 references]

## **Guideline Status**

This is the current release of the guideline.

This guideline updates a previous version: Dill KE, George E, Rybicki FJ, Abbara S, Cummings K, Francois CJ, Gerhard-Herman MD, Gornik HL, Hanley M, Kalva SP, Kirsch J, Kramer CM, Majdalany BS, Moriarty JM, Oliva IB, Schenker MP, Strax R, Expert Panel on Vascular Imaging and Cardiac Imaging. ACR Appropriateness Criteria® imaging for transcatheter aortic valve replacement. [online publication]. Reston (VA): American College of Radiology (ACR); 2013. 12 p. [76 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

## **NEATS** Assessment

National Guideline Clearinghouse (NGC) has assessed this guideline's adherence to standards of trustworthiness, derived from the Institute of Medicine's report Clinical Practice Guidelines We Can Trust.

Poor Fair Good Fill Very Good Very Good Fill Excellent

Assessment	Standard of Trustworthiness
YES	Disclosure of Guideline Funding Source
	Disclosure and Management of Financial Conflict of Interests

	Guideline Development Group Composition
YES	Multidisciplinary Group
YES	Methodologist Involvement
	Patient and Public Perspectives
	Use of a Systematic Review of Evidence
	Search Strategy
	Study Selection
	Synthesis of Evidence
	Evidence Foundations for and Rating Strength of Recommendations
	Grading the Quality or Strength of Evidence
	Benefits and Harms of Recommendations
	Evidence Summary Supporting Recommendations
	Rating the Strength of Recommendations
11111	Specific and Unambiguous Articulation of Recommendations
	External Review
	Updating

# Recommendations

# Major Recommendations

ACR Appropriateness Criteria®

Imaging for Transcatheter Aortic Valve Replacement

<u>Variant 1:</u> Preintervention planning for transcatheter aortic valve replacement at the aortic valve plane.

Procedure	Appropriateness Category	Relative Radiation Level
CTA chest with IV contrast	Usually Appropriate	₩ ₩ ₩
US echocardiography transesophageal	May Be Appropriate	0
MRA chest without IV contrast	May Be Appropriate	0
MRA chest without and with IV contrast	May Be Appropriate	0

CT chest <b>Pritime.duliNé</b> contrast	App NopyrianteAmpess (Cartiergory	Relative Rawiation Level
CT chest with IV contrast	Usually Not Appropriate	⊕ ⊕ ⊕
Aortography thoracic	Usually Not Appropriate	⊕ ⊕ ⊕
CT chest without and with IV contrast	Usually Not Appropriate	♥ ♥ ♥

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

<u>Variant 2:</u> Preintervention planning for transcatheter aortic valve replacement in the supravalvular aorta and iliofemoral system.

Procedure	<b>Appropriateness Category</b>	<b>Relative Radiation Level</b>
CTA abdomen and pelvis with IV contrast	Usually Appropriate	♥ ♥ ♥ ♥
MRA abdomen and pelvis without and with IV contrast	May Be Appropriate	Ο
MRA abdomen and pelvis without IV contrast	May Be Appropriate	0
CT abdomen and pelvis without IV contrast	May Be Appropriate	♥ ♥ ♥
Aortography abdomen and pelvis	May Be Appropriate	♥ ♥ ♥
CT abdomen and pelvis without and with IV contrast	Usually Not Appropriate	♥ ♥ ♥
US intravascular aorta and iliofemoral system	Usually Not Appropriate	0
CT abdomen and pelvis with IV contrast	Usually Not Appropriate	♥ ♥ ♥

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

#### Summary of Literature Review

#### Introduction/Background

Aortic stenosis (AS) is the most frequent type of valvular heart disease in Europe and North America. It primarily presents as calcific AS in adults of advanced age (2%–7% of the population >65 years of age). Although aortic valve replacement (AVR) is a definitive therapy for patients who meet the criteria for severe AS, 32% to 48% of those patients do not undergo conventional AVR due to their advanced age, comorbidities, or prohibitive surgical risk.

Transcatheter aortic valve replacement (TAVR) has dramatically impacted the management of high surgical risk patients by enabling a less invasive approach using a transfemoral, transapical, or other vascular access route to position a prosthesis at the aortic annulus that displaces the native aortic valve leaflets toward the aortic wall. Procedure-related complications are linked to inaccurate estimates of annular geometry; unlike surgical AVR, the aortic annulus is not directly inspected by the proceduralist at the time of the procedure, and multiple parameters related to the annulus should be measured. As the annulus has a complex geometry, volumetric data (computed tomography [CT] in particular) have emerged with standardized reformatting along patient-specific anatomic planes for annular assessment and device sizing.

TAVR planning at or near the aortic annulus is essential because accurate measurements guide optimal choices for device sizing and deployment, with a secondary reduction in TAVR-related complications. Because the transfemoral approach is favored and most commonly used, and because the catheter-based system ranges in size between 14 Fr and 24 Fr, the entire aorta and branches to potential access points

(e.g., the femoral arteries) must be evaluated for the presence, burden, and distribution of peripheral vascular atherosclerosis.

This document has two limitations in scope. First, the panel did not consider the diagnosis of AS or the assessment of coronary artery disease. It is presumed that patients considered in this document are otherwise suitable candidates for TAVR. Second, the panel did not consider planning done at the time of intervention with either catheter angiography, echocardiography done at the time of catheterization, or a combination of both.

Instead, for this document the panel only considered the two clinical tasks required for preprocedure screening: (Variant 1) annular sizing and root evaluation to see if a device is suitable for deployment for patients with no past history of aortic valve surgery or prior TAVR, and then to help guide the choice of the valve prosthesis, considering and minimizing potential complications via multiple measurements; and (Variant 2) imaging the remainder of the aorta and iliofemoral arteries to determine the feasibility of the preferred transfemoral approach, and when this route is high risk, to assess potential alternate access routes.

Discussion of Procedures by Variant

Variant 1: Preintervention Planning for TAVR at the Aortic Valve Plane

#### CT and CTA

Retrospectively electrocardiogram (ECG)-gated CT angiography (CTA) is the first-line modality for preprocedural annular sizing, as it enables direct planimetry and reference standard measurements for all required annular parameters for TAVR deployment. Multiple single- and multicenter trials have consistently shown that integration of CTA in preprocedural planning helps reduce the rate of significant paravalvular regurgitation and also allows for the discrimination of risk of annular rupture, coronary occlusion, and vascular injury. Guiding optimum fluoroscopic projections with co-planar angles of the aortic root facilitates appropriate valve deployment. In addition, CTA provides data regarding the distribution of valve calcification. Whereas vascular access is typically extracardiac (and evaluated in the second variant), when introduction of the TAVR system via the cardiac apex is being considered, CTA is essential for planning.

Noncontrast CT can be used to evaluate valve calcification; however, the incremental role in procedural planning remains uncertain, its primary role is in assisting the diagnosis of AS and not for guiding TAVR. When iodinated contrast is absolutely contraindicated, an alternate method for TAVR planning is generally required. For the large majority of patients who undergo CT for TAVR planning, contrast is administered for first-pass CTA (CTA chest with intravenous [IV] contrast) so that the annular size and related measurements can be performed after image postprocessing. There is essentially no role for imaging the chest after the first pass of contrast or for performing this acquisition after a noncontrast study (CT chest without and with IV contrast).

For the purposes of distinguishing between CT and CTA, the ACR Appropriateness Criteria topics use the definition in the Practice Parameter for the Performance and Interpretation of Body Computed Tomography Angiography (CTA) : "CTA uses a thin-section CT acquisition that is timed to coincide with peak arterial or venous enhancement. The resultant volumetric dataset is interpreted using primary transverse reconstructions as well as multiplanar reformations and 3-D renderings."

All procedure elements are essential: (1) timing, (2) recons/reformats, and (3) 3-D renderings. Standard CTs with contrast also include timing issues and recons/reformats. Only in CTA, however, is 3-D rendering a required element. This corresponds to the definitions that CMS has applied to the Current Procedural Terminology (CPT) codes.

#### Echocardiography

Although 2-D transesophageal echocardiography was the initial method of choice for annular sizing, this method has been replaced with 3-D acquisitions to help with annular sizing. Annular measurements are

reproducible and correlate with reference standard CTA. Compared to CT, there is significantly less data for evaluating root features such as coronary ostial height and the presence or absence of sub-annular calcification. It is more commonly used at the time of the procedure, utilization that is not being assessed in this guideline, rather than for planning. In the setting of contraindications for CT such as anaphylaxis and severe renal dysfunction, 3-D transesophageal echocardiography is commonly used to assess annular geometry and size. Of note, when echocardiography is used for TAVR planning, transthoracic acquisition (though used in the diagnosis of AS) is not used and was not considered in ratings.

#### **MRA**

Although magnetic resonance angiography (MRA) provides highly accurate, low variability annular measurements for patients undergoing surgical AVR, there is only modest clinical adoption, and there is a paucity of supporting data for TAVR planning compared to CTA. MRA-based measurements do correlate with CT; therefore, MRA could be an alternative to CTA when there is a severe iodine-based contraindication. MRA approaches are limited when there is high-susceptibility artifact, magnetic field-incompatible devices, claustrophobia, and severe arrhythmia. Finally, the MRA examination is substantially longer than the CT acquisition, which can be problematic for patients with a poor clinical condition.

#### Aortography

Whereas catheterization images acquired at the time of the procedure are necessary and complementary to planning, increasing data questions the need to perform preprocedural catheterization, based on the fact that all necessary parameters can typically be extracted from the CT images. Specifically, the 2-D projections may not adequately reflect the complex geometry of the aortic annulus. Instead, catheterization images focus on the assessment of root geometry and coronary height.

Variant 2: Preintervention Planning for TAVR in the Supravalvular Aorta and Iliofemoral System

#### CT and CTA

CTA acquisition with isotropic voxels enables image postprocessing to accurately depict geometry, lumen size, and the presence of dissections, atherosclerotic disease, and subsequent stenosis from the entire arterial system between the supravalvular aorta and the femoral arteries, the preferred TAVR access point. CTA also best identifies concentric or horseshoe calcification that is a relative contraindication for TAVR, especially in those with borderline vessel diameter. CTA is also essential for atypical TAVR apparatus access points such as transaortic or transcaval approaches.

Whereas CTA is preferred for patients with a strong contraindication to contrast injection, noncontrast imaging can be used to evaluate calcification within the aorta and including the iliofemoral arteries under evaluation for access. If a patient receives IV contrast, CTA images should be acquired, as opposed to later phase imaging (CT abdomen and pelvis with IV contrast). Moreover, there would be no role for performing this acquisition after a noncontrast study (CT abdomen and pelvis without and with IV contrast).

#### <u>Aortography</u>

Though catheter angiography allows assessment of luminal size, it provides limited evaluation of the arterial wall for plaque burden and calcification. Standard catheter angiography is also limited in that it is typically planar and therefore is limited in its capacity to evaluate tortuosity and for the detection of eccentric stenosis. Angiography also plays a limited role in the evaluation of patients for whom alternate access is being considered.

#### <u>IVUS</u>

Whereas ultrasound (US) is often used to facilitate arterial puncture, surface-based sonography is insufficient to comprehensively assess arterial size, calcification, and tortuosity of the iliofemoral system and the aorta. There is little or no data regarding the usefulness of intravascular US (IVUS) for TAVR

planning. Studies in abdominal aortic aneurysm subjects suggest that IVUS provides reliable information of aortoiliofemoral anatomy, especially luminal dimension, presence of and morphology of atherosclerotic plaque, and calcification.

#### MRA

MRA provides an alternative to CT for evaluation of the aorta and iliofemoral arteries. However, it is limited in the assessment of vascular calcification.

#### Summary of Recommendations

Preintervention planning for TAVR at the aortic valve plane: 3-D cross sectional imaging of the aortic annular plane is essential with CTA of the chest with IV contrast being the first-line modality. Preintervention planning for TAVR in the supravalvular aorta and iliofemoral system: CTA abdomen and pelvis with IV contrast is the preferred and first-line modality for vascular access assessment to identify those patients with potential risk for compromised intra-procedural vascular access.

#### Abbreviations

CTA, computed tomography angiography IV, intravenous MRA, magnetic resonance angiography US, ultrasound

Relative Radiation Level Designations

Relative Radiation Level*	Adult Effective Dose Estimate Range	Pediatric Effective Dose Estimate Range
0	0 mSv	0 mSv
❤	<0.1 mSv	<0.03 mSv
♥ ♥	0.1-1 mSv	0.03-0.3 mSv
♥ ♥ ♥	1-10 mSv	0.3-3 mSv
♥ ♥ ♥	10-30 mSv	3-10 mSv
<b>***</b>	30-100 mSv	10-30 mSv

<sup>\*</sup>RRL assignments for some of the examinations cannot be made, because the actual patient doses in these procedures vary as a function of a number of factors (e.g., region of the body exposed to ionizing radiation, the imaging guidance that is used). The RRLs for these examinations are designated as "Varies."

## Clinical Algorithm(s)

Algorithms were not developed from criteria guidelines.

## Scope

# Disease/Condition(s)

Aortic stenosis requiring transcatheter aortic valve replacement

## **Guideline Category**

Evaluation

## Clinical Specialty

Cardiology

Family Practice

Internal Medicine

Radiology

Thoracic Surgery

## **Intended Users**

Advanced Practice Nurses

Health Care Providers

Hospitals

Managed Care Organizations

Physician Assistants

**Physicians** 

Students

**Utilization Management** 

# Guideline Objective(s)

To evaluate the appropriateness of preintervention imaging procedures for transcatheter aortic valve replacement

Note: The panel did not consider planning done at the time of intervention with either catheter angiography, echocardiography done at the time of catheterization, or a combination of both.

## **Target Population**

Patients with aortic stenosis (AS) requiring transcatheter aortic valve replacement (TAVR)

Note: The panel did not consider the diagnosis of AS or the assessment of coronary artery disease. It is presumed that patients considered in the Appropriateness Criteria document are otherwise suitable candidates for TAVR.

#### Interventions and Practices Considered

- 1. Computed tomography angiography (CTA)
  - Chest with intravenous (IV) contrast
  - Abdomen and pelvis with IV contrast
- 2. Ultrasound (US)
  - Echocardiography transesophageal
  - Intravascular aorta and iliofemoral system
- 3. Magnetic resonance angiography (MRA)
  - Chest without and with IV contrast

- Chest without IV contrast
- Abdomen and pelvis without and with IV contrast
- Abdomen and pelvis without IV contrast
- 4. Computed tomography (CT)
  - Chest without IV contrast
  - · Chest with IV contrast
  - Chest without and with IV contrast
  - Abdomen and pelvis without IV contrast
  - Abdomen and pelvis with IV contrast
  - Abdomen and pelvis without and with IV contrast
- 5. Aortography
  - Thoracic
  - Abdomen and pelvis

## Major Outcomes Considered

- Utility of imaging procedures for preintervention planning for transcatheter aortic valve replacement
- Accuracy of imaging procedures for preintervention planning for transcatheter aortic valve replacement

# Methodology

## Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

## Description of Methods Used to Collect/Select the Evidence

#### Literature Search Summary

Of the 75 citations in the original bibliography, 26 were retained in the final document.

A literature search was conducted in March 2015 and June 2017 to identify additional evidence published since the ACR Appropriateness Criteria® Imaging for Transcatheter Aortic Valve Replacement topic was finalized. Using the search strategies described in the literature search companion (see the "Availability of Companion Documents" field), 578 articles were found. Four articles were added to the bibliography. The remaining articles were not used due to either poor study design, the articles were not relevant or generalizable to the topic, or the results were unclear or biased.

The author added 16 citations from bibliographies, Web sites, or books that were not found in the literature searches.

Two citations are supporting documents that were added by staff.

See also the American College of Radiology (ACR) Appropriateness Criteria® literature search process document (see the "Availability of Companion Documents" field) for further information.

#### Number of Source Documents

Of the 75 citations in the original bibliography, 26 were retained in the final document. The literature search conducted in March 2015 and June 2017 found 4 articles that were added to the bibliography. The author added 16 citations from bibliographies, Web sites, or books that were not found in the literature searches. Two citations are supporting documents that were added by staff.

## Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

## Rating Scheme for the Strength of the Evidence

Definitions of Study Quality Categories

Category 1 - The study is well-designed and accounts for common biases.

Category 2 - The study is moderately well-designed and accounts for most common biases.

Category 3 - The study has important study design limitations.

Category 4 - The study or source is not useful as primary evidence. The article may not be a clinical study, the study design is invalid, or conclusions are based on expert consensus.

The study does not meet the criteria for or is not a hypothesis-based clinical study (e.g., a book chapter or case report or case series description);

Or

The study may synthesize and draw conclusions about several studies such as a literature review article or book chapter but is not primary evidence;

Or

The study is an expert opinion or consensus document.

Category M - Meta-analysis studies are not rated for study quality using the study element method because the method is designed to evaluate individual studies only. An "M" for the study quality will indicate that the study quality has not been evaluated for the meta-analysis study.

## Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

## Description of the Methods Used to Analyze the Evidence

The topic author assesses the literature then drafts or revises the narrative summarizing the evidence found in the literature. American College of Radiology (ACR) staff drafts an evidence table based on the analysis of the selected literature. These tables rate the study quality for each article included in the narrative.

The expert panel reviews the narrative, evidence table and the supporting literature for each of the topic-variant combinations and assigns an appropriateness rating for each procedure listed in the variant table(s). Each individual panel member assigns a rating based on his/her interpretation of the available evidence.

More information about the evidence table development process can be found in the ACR Appropriateness Criteria® Evidence Table Development document (see the "Availability of Companion Documents" field).

### Methods Used to Formulate the Recommendations

Expert Consensus (Delphi)

## Description of Methods Used to Formulate the Recommendations

#### Overview

The purpose of the rating rounds is to systematically and transparently determine the panels' recommendations while mitigating any undue influence of one or more panel members on another individual panel members' interpretation of the evidence. The panel member's rating is determined by reviewing the evidence presented in the Summary of Literature Review and assessing the risks or harms of performing the procedure or treatment balanced with the benefits of performing the procedure or treatment. The individual panel member ratings are used to calculate the median rating, which determines the panel's rating. The assessment of the amount of deviation of individual ratings from the panel rating determines whether there is disagreement among the panel about the rating.

The process used in the rating rounds is a modified Delphi method based on the methodology described in the RAND/UCLA Appropriateness Method User Manual.

The appropriateness is rated on an ordinal scale that uses integers from 1 to 9 grouped into three categories (see the "Rating Scheme for the Strength of the Recommendations" field).

#### Determining the Panel's Recommendation

Ratings represent an individual's assessment of the risks and benefits of performing a specific procedure for a specific clinical scenario on an ordinal scale. The recommendation is the appropriateness category (i.e., "Usually appropriate," "May be appropriate," or "Usually not appropriate").

The appropriateness category for a procedure and clinical scenario is determined by the panel's median rating without disagreement (see below for definition of disagreement). The panel's median rating is calculated after each rating round. If there is disagreement after the second rating round, the rating category is "May be appropriate (Disagreement)" with a rating of "5" so users understand the group disagreed on the final recommendation. The actual panel median rating is documented to provide additional context.

Disagreement is defined as excessive dispersion of the individual ratings from the group (in this case, an Appropriateness Criteria [AC] panel) median as determined by comparison of the interpercentile range (IPR) and the interpercentile range adjusted for symmetry (IPRAS). In those instances when the IPR is greater than the IPRAS, there is disagreement. For a complete discussion, please refer to chapter 8 of the RAND/UCLA Appropriateness Method User Manual.

Once the final recommendations have been determined, the panel reviews the document. If two thirds of the panel feel a final recommendation is wrong (e.g., does not accurately reflect the evidence, may negatively impact patient health, has unintended consequences that may harm health care, etc.) and the process must be started again from the beginning.

For additional information on the ratings process see the Rating Round Information document (see the "Availability of Companion Documents" field).

Additional methodology documents, including a more detailed explanation of the complete topic
development process and all ACR AC topics can be found on the ACR Web site
(see also the "Availability of Companion Documents" field).

## Rating Scheme for the Strength of the Recommendations

Appropriateness Category Names and Definitions

Appropriateness Category Name	Appropriateness Rating	Appropriateness Category Definition
Usually Appropriate	7, 8, or 9	The imaging procedure or treatment is indicated in the specified clinical scenarios at a favorable risk-benefit ratio for patients.
May Be Appropriate	4, 5, or 6	The imaging procedure or treatment may be indicated in the specified clinical scenarios as an alternative to imaging procedures or treatments with a more favorable risk-benefit ratio, or the risk-benefit ratio for patients is equivocal.
May Be Appropriate (Disagreement)	5	The individual ratings are too dispersed from the panel median. The different label provides transparency regarding the panel's recommendation. "May be appropriate" is the rating category and a rating of 5 is assigned.
Usually Not Appropriate	1, 2, or 3	The imaging procedure or treatment is unlikely to be indicated in the specified clinical scenarios, or the risk-benefit ratio for patients is likely to be unfavorable.

## Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

## Method of Guideline Validation

Internal Peer Review

## Description of Method of Guideline Validation

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria.

# Evidence Supporting the Recommendations

## Type of Evidence Supporting the Recommendations

The recommendations are based on analysis of the current medical evidence literature and the application of the RAND/UCLA appropriateness method and expert panel consensus.

#### Summary of Evidence

Of the 48 references cited in the ACR Appropriateness Criteria® Imaging for Transcatheter Aortic Valve Replacement document, 15 are categorized as therapeutic references including 4 well-designed studies, and 6 good-quality studies. Additionally, 33 references are categorized as diagnostic references including 2 well-designed studies, 11 good-quality studies, and 7 quality studies that may have design limitations. There are 18 references that may not be useful as primary evidence.

Although there are references that report on studies with design limitations, 23 well-designed or good-quality studies provide good evidence.

# Benefits/Harms of Implementing the Guideline Recommendations

#### Potential Benefits

- Reduced rate of procedural complications
- Multiple single- and multicenter trials have consistently shown that integration of computed tomography angiography (CTA) in preprocedural planning helps reduce the rate of significant paravalvular regurgitation and also allows for the discrimination of risk of annular rupture, coronary occlusion, and vascular injury.

#### Potential Harms

#### Relative Radiation Level Information

Potential adverse health effects associated with radiation exposure are an important factor to consider when selecting the appropriate imaging procedure. Because there is a wide range of radiation exposures associated with different diagnostic procedures, a relative radiation level (RRL) indication has been included for each imaging examination. The RRLs are based on effective dose, which is a radiation dose quantity that is used to estimate population total radiation risk associated with an imaging procedure. Patients in the pediatric age group are at inherently higher risk from exposure, both because of organ sensitivity and longer life expectancy (relevant to the long latency that appears to accompany radiation exposure). For these reasons, the RRL dose estimate ranges for pediatric examinations are lower as compared to those specified for adults. Additional information regarding radiation dose assessment for imaging examinations can be found in the American College of Radiology (ACR) Appropriateness Criteria® Radiation Dose Assessment Introduction document (see the "Availability of Companion Documents" field).

## Contraindications

#### Contraindications

- Anaphylaxis and severe renal dysfunction are contraindications to computed tomography (CT).
- Concentric or horseshoe calcification is a relative contraindication for transcatheter aortic valve replacement (TAVR), especially in those with borderline vessel diameter.

# Qualifying Statements

## Qualifying Statements

- The American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those examinations generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.
- ACR seeks and encourages collaboration with other organizations on the development of the ACR

Appropriateness Criteria through society representation on expert panels. Participation by representatives from collaborating societies on the expert panel does not necessarily imply society endorsement of the final document.

# Implementation of the Guideline

## Description of Implementation Strategy

An implementation strategy was not provided.

# Institute of Medicine (IOM) National Healthcare Quality Report Categories

## IOM Care Need

Getting Better

Living with Illness

#### **IOM Domain**

Effectiveness

# Identifying Information and Availability

# Bibliographic Source(s)

Leipsic JA, Blanke P, Hanley M, Batlle JC, Bolen MA, Brown RKJ, Desjardins B, Eberhardt RT, Gornik HL, Hurwitz LM, Maniar H, Patel HJ, Sheybani EF, Steigner ML, Verma N, Abbara S, Rybicki FJ, Kirsch J, Dill KE, Expert Panel on Cardiac Imaging and Vascular Imaging. ACR Appropriateness Criteria® imaging for transcatheter aortic valve replacement. Reston (VA): American College of Radiology (ACR); 2017. 8 p. [48 references]

## Adaptation

Not applicable: The guideline was not adapted from another source.

#### Date Released

2017

## Guideline Developer(s)

American College of Radiology - Medical Specialty Society

# Source(s) of Funding

The funding for the process is assumed entirely by the American College of Radiology (ACR). ACR staff support the expert panels through the conduct of literature searches, acquisition of scientific articles, drafting of evidence tables, dissemination of materials for the Delphi process, collation of results, conference calls, document processing, and general assistance to the panelists.

#### Guideline Committee

Committee on Appropriateness Criteria, Expert Panels on Cardiac Imaging and Vascular Imaging

## Composition of Group That Authored the Guideline

Panel Members: Jonathon A. Leipsic, MD (Principal Author); Philipp Blanke, MD (Research Author); Michael Hanley, MD (Panel Vice-chair [Vascular]); Juan C. Batlle, MD; Michael A. Bolen, MD; Richard K. J. Brown, MD; Benoit Desjardins, MD, PhD; Robert T. Eberhardt, MD; Heather L. Gornik, MD; Lynne M. Hurwitz, MD; Hersh Maniar, MD; Himanshu J. Patel, MD; Elizabeth F. Sheybani, MD; Michael L. Steigner, MD; Nupur Verma, MD; Suhny Abbara, MD (Specialty Chair [Cardiac]); Frank J. Rybicki, MD, PhD (Specialty Chair [Vascular]); Jacobo Kirsch, MD (Panel Chair [Cardiac]); Karin E. Dill, MD (Panel Chair [Vascular])

## Financial Disclosures/Conflicts of Interest

Disclosing Potential Conflicts of Interest and Management of Conflicts of Interest

interest. In 2016, the American College of Radiology (ACR) began an organization-wide review of its
conflict of interest (COI) policies. The current ACR COI policy is available on its Web site
. The Appropriateness Criteria (AC) program's COI process varies from the
organization's current policy to accommodate the requirements for qualified provider-led entities as
designated by the Centers for Medicare and Medicaid Services' Appropriate Use Criteria (AUC) program.
When physicians become participants in the AC program, welcome letters are sent to inform them of their panel roles and responsibilities, including a link to complete the COI form The
COI form requires disclosure of all potential conflicts of interest. ACR staff oversees the COI evaluation
process, coordinating with review panels consisting of ACR staff and members, who determine when there
is a conflict of interest and what action, if any, is appropriate. In addition to making the information
publicly available, management may include exclusion from some topic processes, exclusion from a topic,
or exclusion from the panel.

An important aspect of committee operations is the disclosure and management of potential conflicts of

Besides potential COI disclosure, AC staff begins every committee call with the conflict of interest disclosure statement listed below reminding members to update their COI forms. If any updates to their COI information have not been submitted, they are instructed not to participate in discussion where an undisclosed conflict may exist.

Finally, all ACR AC are published as part of the Journal of the American College of Radiology (JACR) electronic supplement. Those who participated on the document and are listed as authors must complete the JACR process that includes completing the International Committee of Medical Journal Editors (ICMJE) COI form which is reviewed by the journal's staff/publisher.

Dr. Blanke reports personal fees from Edwards Lifesciences, personal fees from Tendyne, personal fees from Circle Cardiovascular Imaging, and personal fees from Neovasc, outside the submitted work. Dr. Gornik reports that she has a patent non invasive diagnostics/ABI measurement pending, is a Member of the Board of Directors of Intersocietal Accreditation Commission–Vascular Testing Division, and has received research funding for site research from Astra Zeneca. The other authors have no conflicts of interest related to the material discussed in this article.

## **Guideline Status**

This is the current release of the guideline.

This guideline updates a previous version: Dill KE, George E, Rybicki FJ, Abbara S, Cummings K, Francois CJ, Gerhard-Herman MD, Gornik HL, Hanley M, Kalva SP, Kirsch J, Kramer CM, Majdalany BS, Moriarty JM, Oliva IB, Schenker MP, Strax R, Expert Panel on Vascular Imaging and Cardiac Imaging. ACR Appropriateness Criteria® imaging for transcatheter aortic valve replacement. [online publication]. Reston (VA): American College of Radiology (ACR); 2013. 12 p. [76 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

## Guideline Availability

Available from the American College of Radiology (ACR) Web site

## Availability of Companion Documents

The following are available:

ACR Appropriateness Criteria®. Overview. Reston (VA): American College of Radiology; 2017.
Available from the American College of Radiology (ACR) Web site
ACR Appropriateness Criteria®. Literature search process. Reston (VA): American College of
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#### Patient Resources

None available

#### **NGC Status**

This NGC summary was completed by ECRI Institute on March 7, 2014. The guideline developer agreed to not review the content. This summary was updated on May 10, 2018. The guideline developer agreed to not review the content.

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